

MCKESSON

Controlled Substance Monitoring

Discount Drug Mart

September 29th, 2017

Nate Hartle

Sr. Director – Regulatory Affairs



BUSINESS
CARE
CONNECTIVITY

MCKMDL00448596

Exhibit C

Agenda



Scope of Problem

Industry Updates

Regulatory Responsibilities

McKesson's CSMP

Discount Drug Mart Program Overview

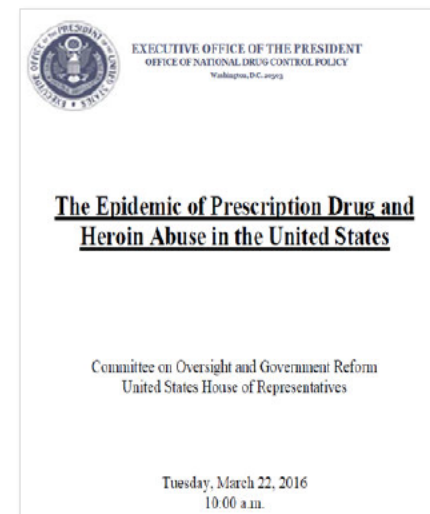
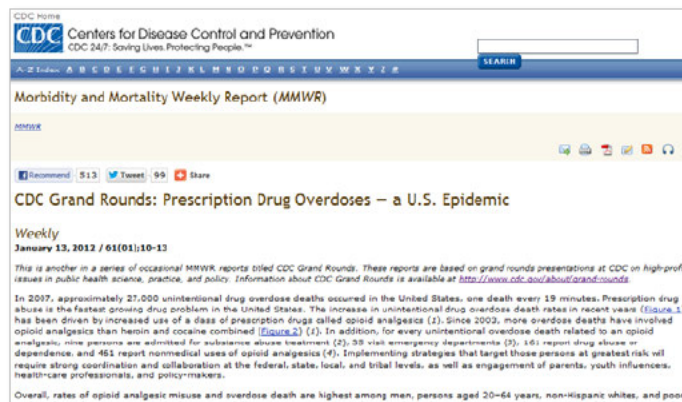
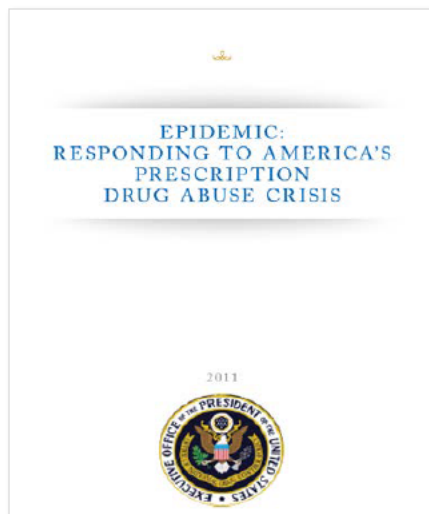
Q & A | Open Discussion

Scope of the Problem | Epidemic

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“The drug problems of past decades pale when compared to the current opioid epidemic which has killed 165,000 Americans from 2000 to 2014.”







Source: National Safety Council. *Prescription Nation 2016: Addressing America's Drug Epidemic*. Retrieved November 7, 2016, from National Safety Council: <http://www.nsc.org/RxDrugOverdoseDocuments/Prescription-Nation-2016-American-Drug-Epidemic.pdf>

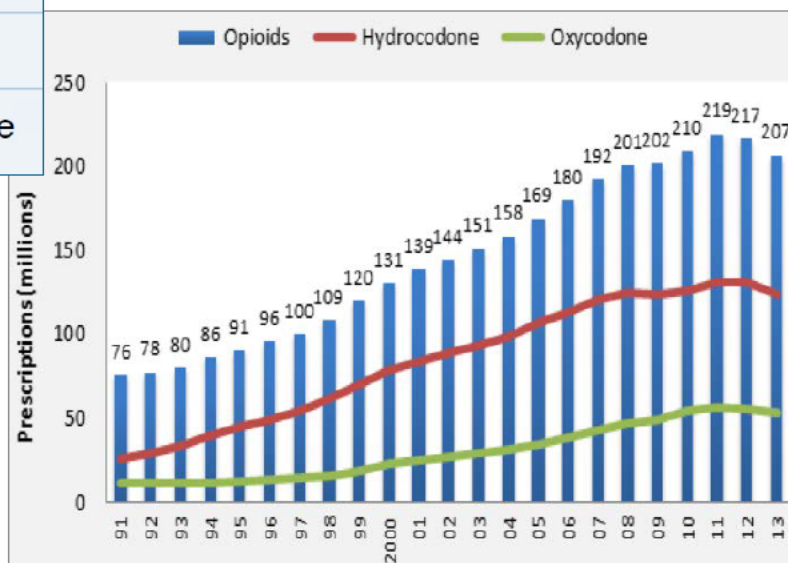
Scope of the Problem | Opioid Prescribing & Abuse

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On an average day in the U.S.:

-  More than **650,000 opioid prescriptions** dispensed
-  **3,900 people** initiate nonmedical use of prescription opioids
-  **580 people** initiate heroin use
-  **78 people** die from an opioid-related overdose

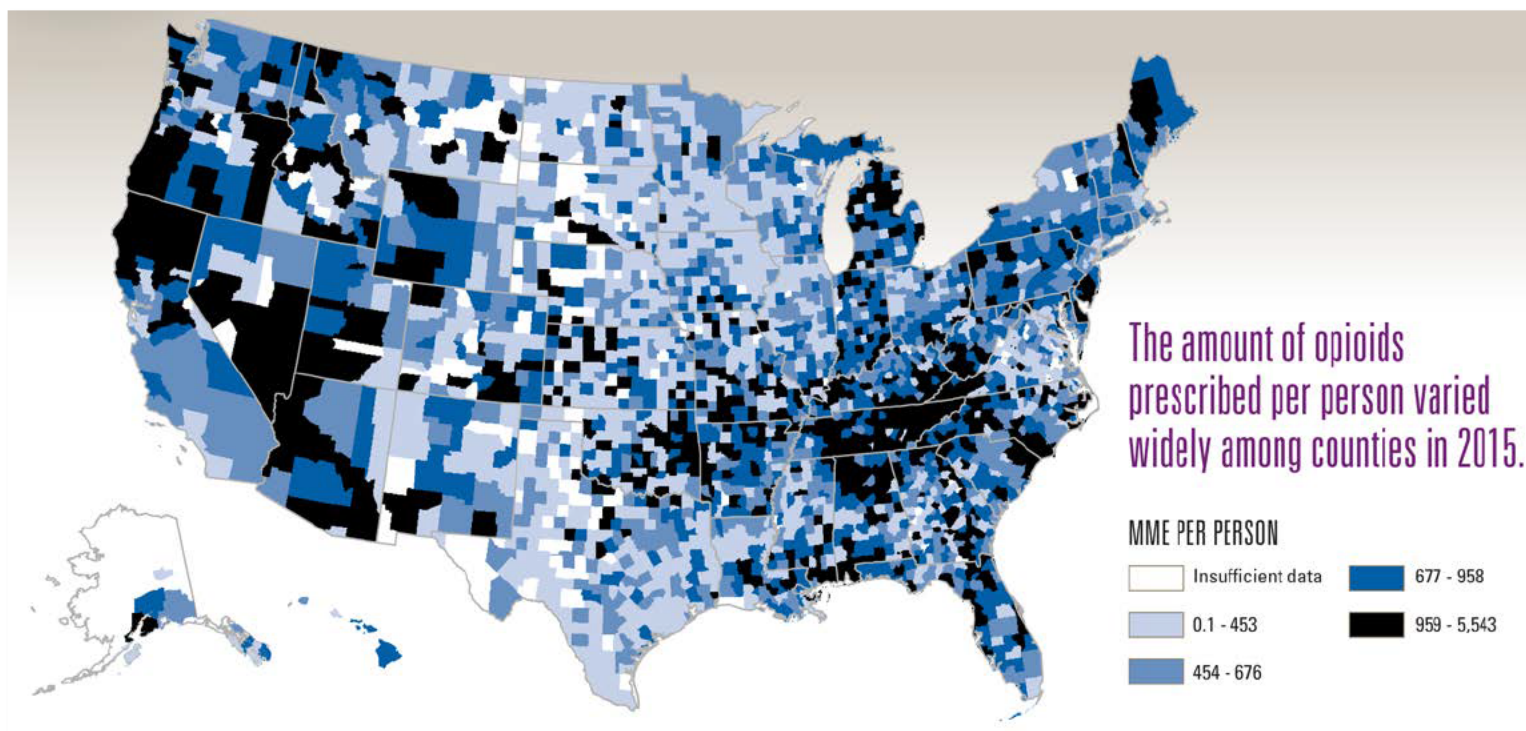
Opioid Prescriptions Dispensed by Retail Pharmacies, 1991 – 2013



Source 1: Department of Health & Human Services. *The Opioid Epidemic: By the Numbers*. Retrieved November 7, 2016, from Department of Health & Human Services: <http://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf>

Source 2: NIH: National Institute on Drug Abuse. *Prescription Opioid & Heroin Abuse*. Retrieved November 14, 2016, from NIH: National Institute on Drug Abuse: <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/prescription-opioid-heroin-abuse>

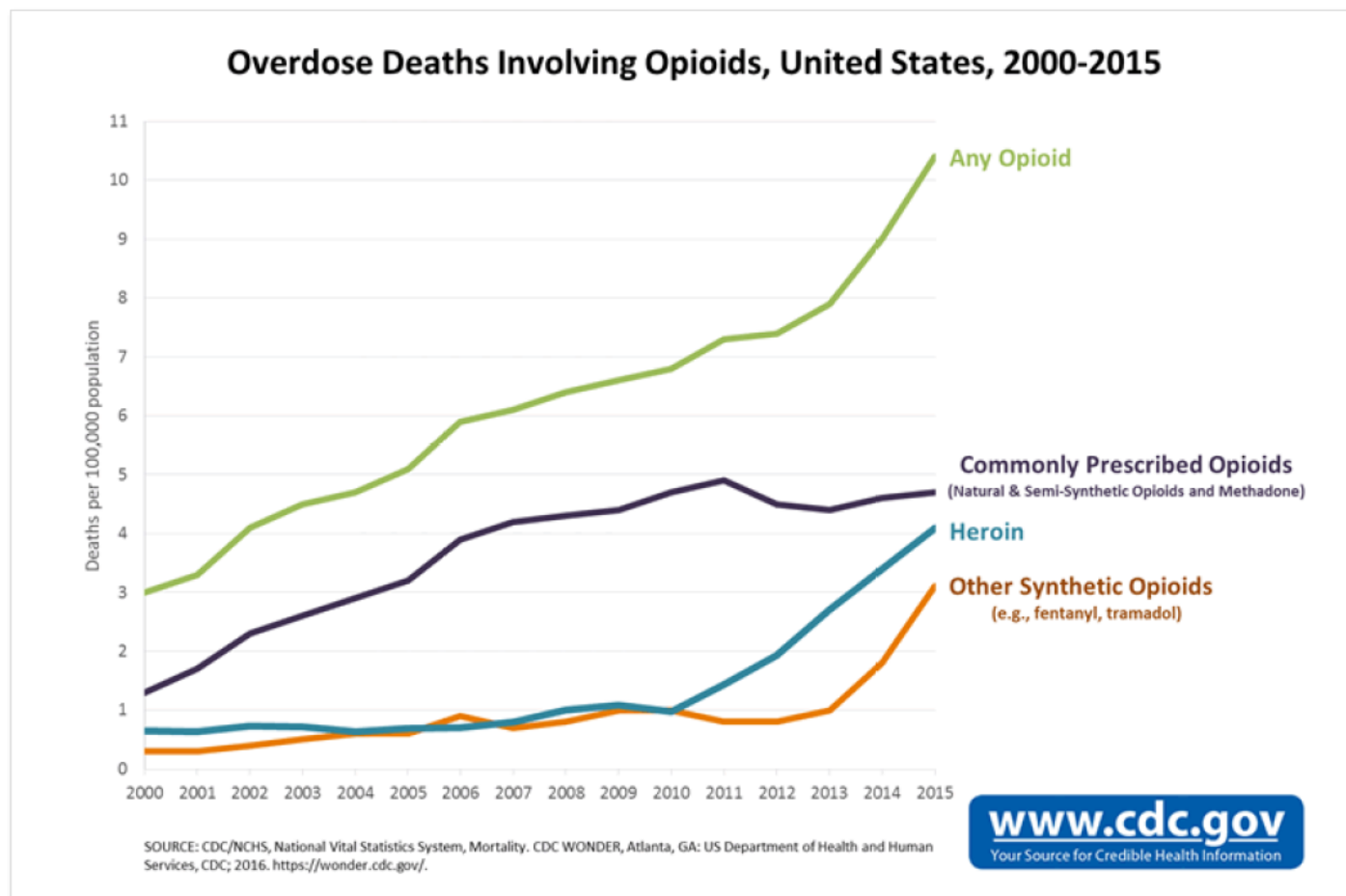
Scope of the Problem | Opioid Prescribing & Abuse

McKesson

Source: Centers for Disease Control and Prevention, Vital Signs July 2017. *Opioid Prescribing – Where you live matters*. Retrieved August 22, 2017 from Centers for Disease Control and Prevention: <https://www.cdc.gov/vitalsigns/pdf/2017-07-vitalsigns.pdf>

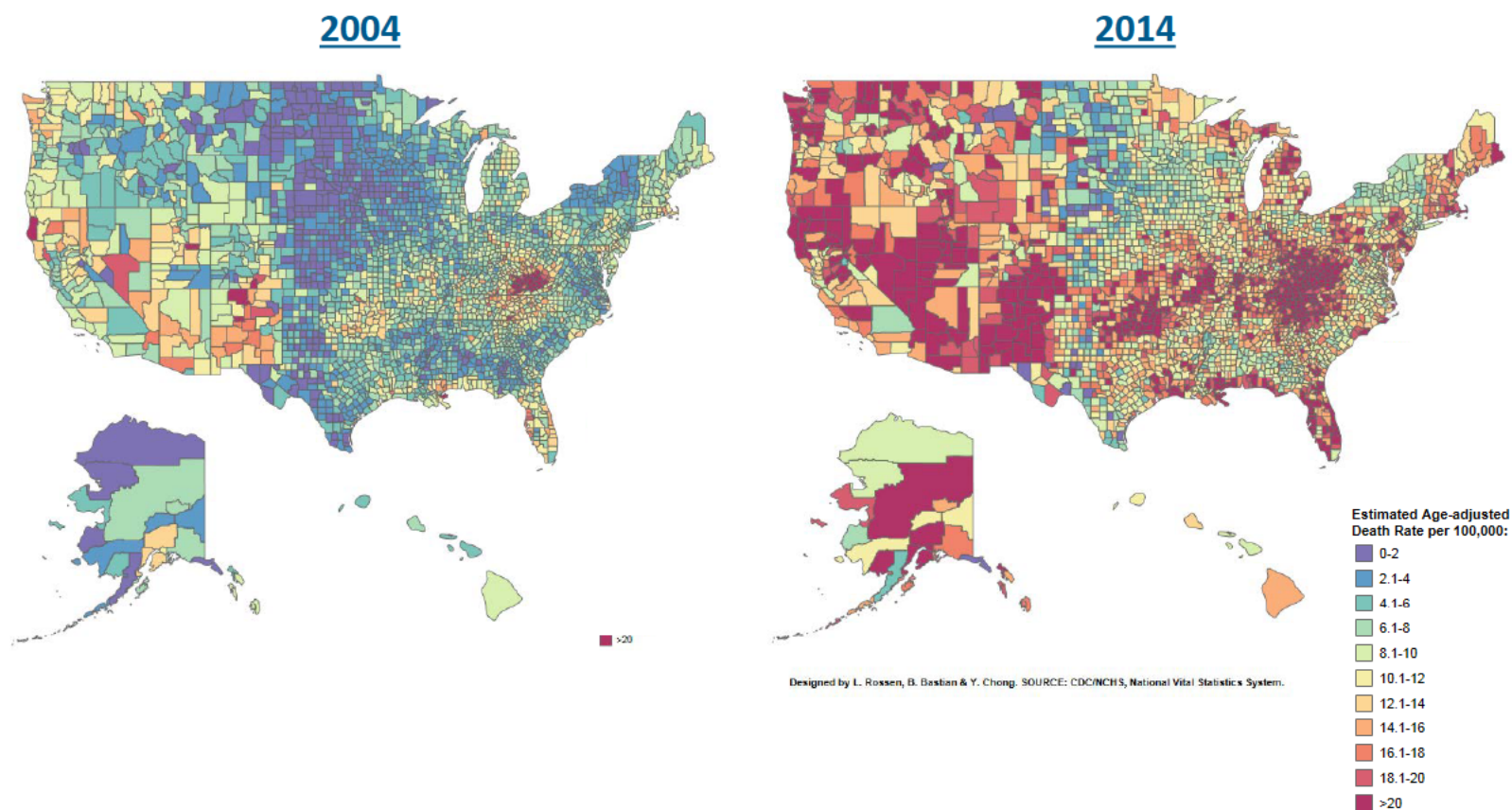
Scope of the Problem | Overdose Death Statistics

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Scope of the Problem | Overdose Death Statistics

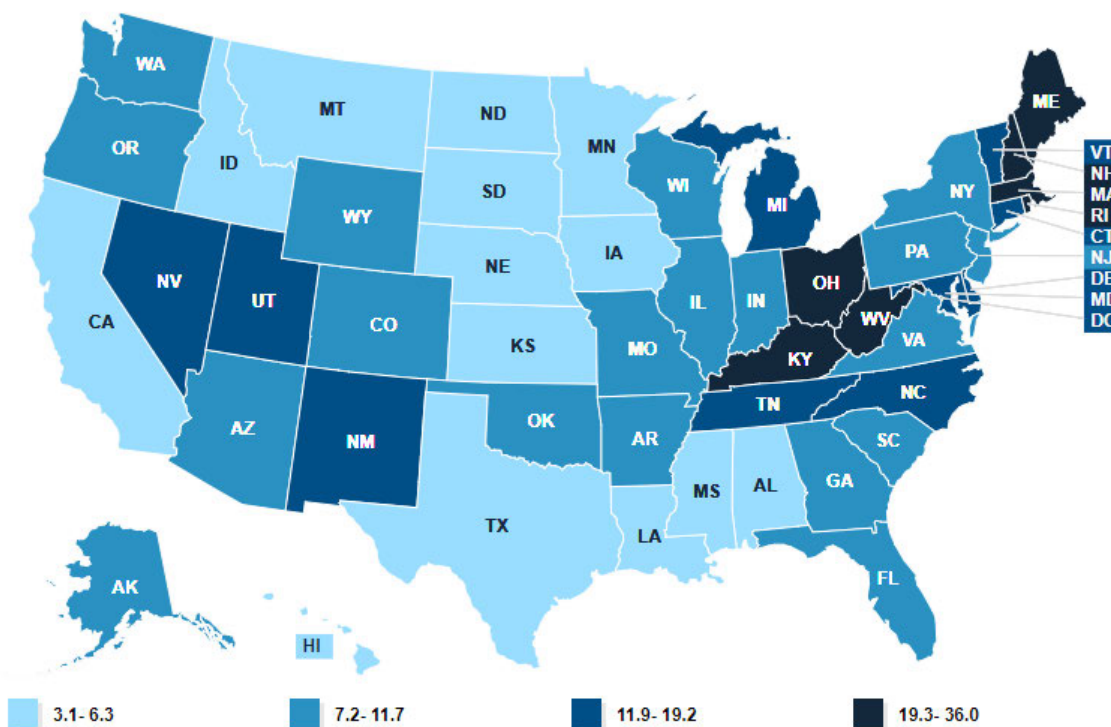
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Source: Centers for Disease Control and Prevention, NCHS Data Visualization Gallery. *Drug Poisoning Mortality: United States, 1999–2014*. Retrieved November 14, 2016, from Centers for Disease Control and Prevention: <https://blogs.cdc.gov/nchs-data-visualization/drug-poisoning-mortality/>

Scope of the Problem | Overdose Death Statistics (2015) **McKESSON**

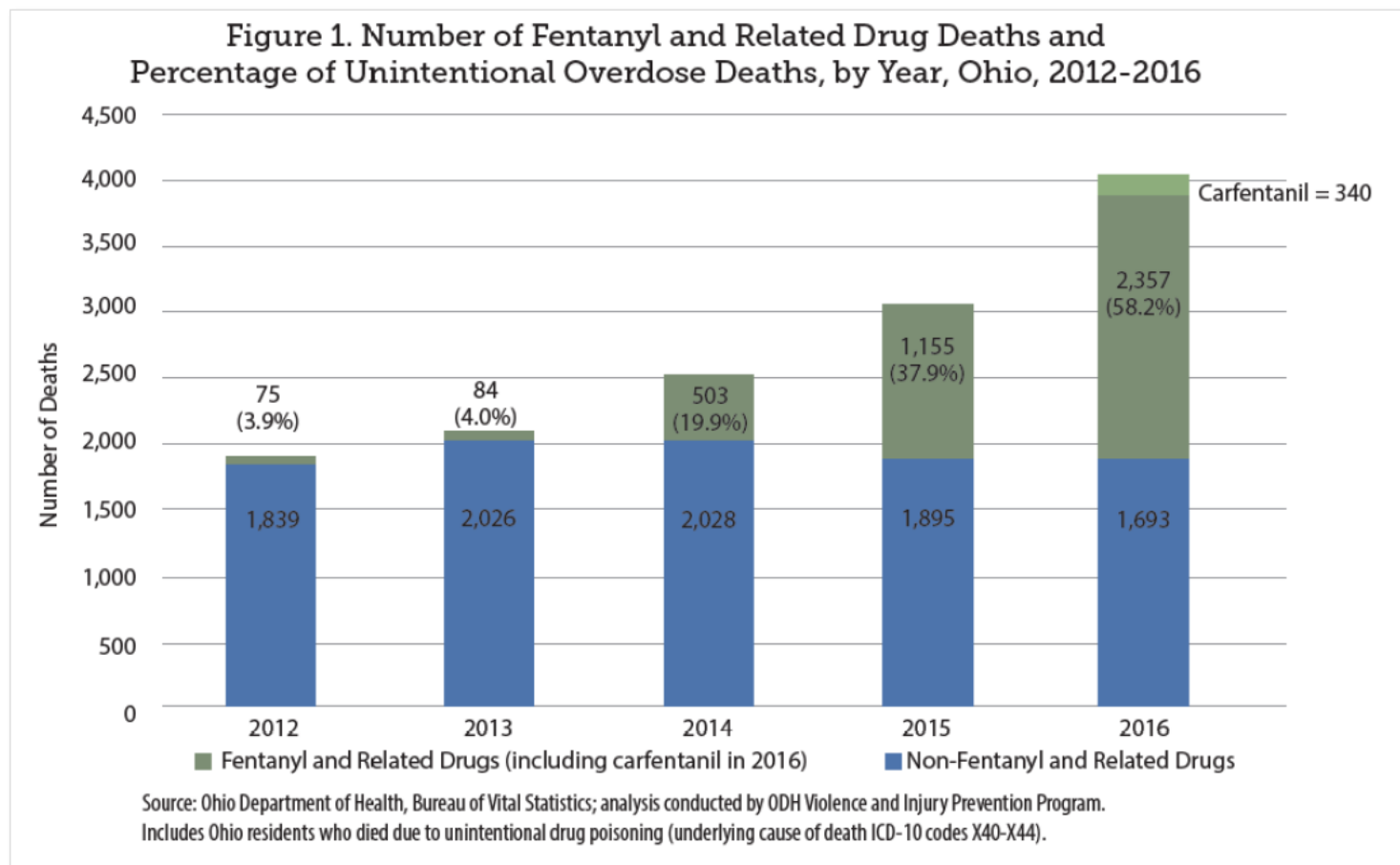
Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted)



Source: Kaiser Family Foundation analysis of Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. Multiple Cause of Death 1999-2015 on CDC WONDER Online Database, released 2016. Data are from the Multiple Cause of Death Files, 1999-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://www.kff.org/other/state-indicator/opioid-overdose-death-rates> on August 23, 2017.

Ohio | 2016 Data

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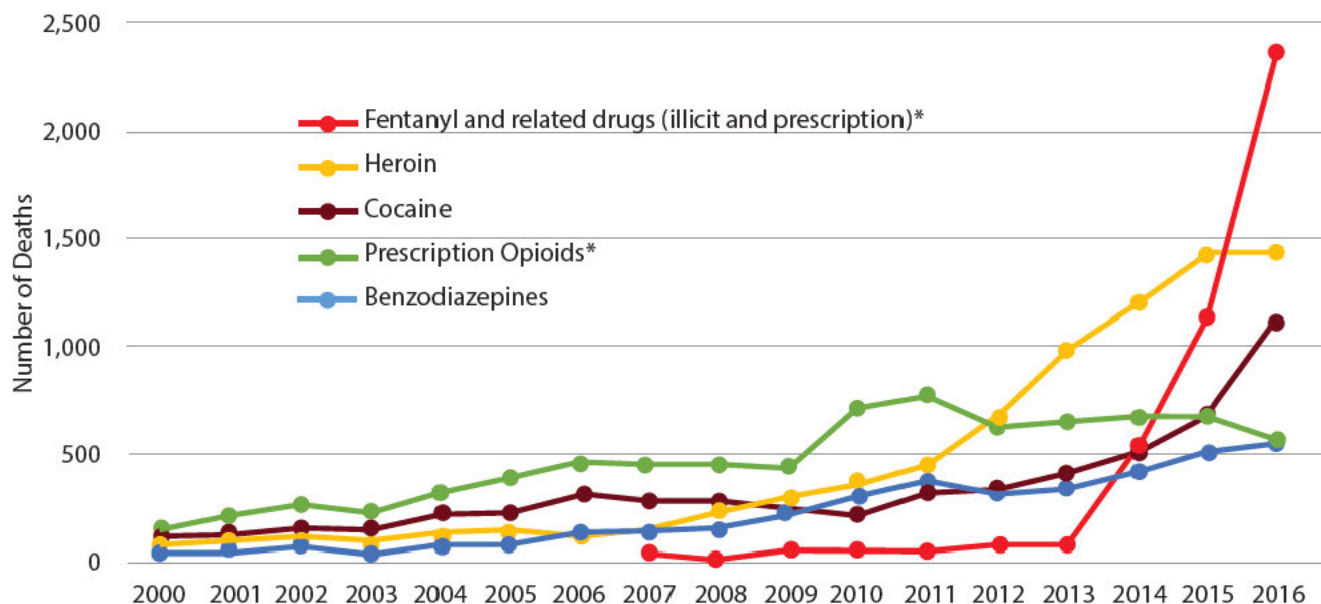


Source: Ohio Department of Health. Drug Overdose Data and Publications. Retrieved September 29, 2017, from <http://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf?la=en> Department of Health & Human Services: <http://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf>

Ohio | 2016 Data

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Figure 7. Number of Unintentional Drug Overdose Deaths Involving Selected Drugs, by Year, Ohio, 2000-2016



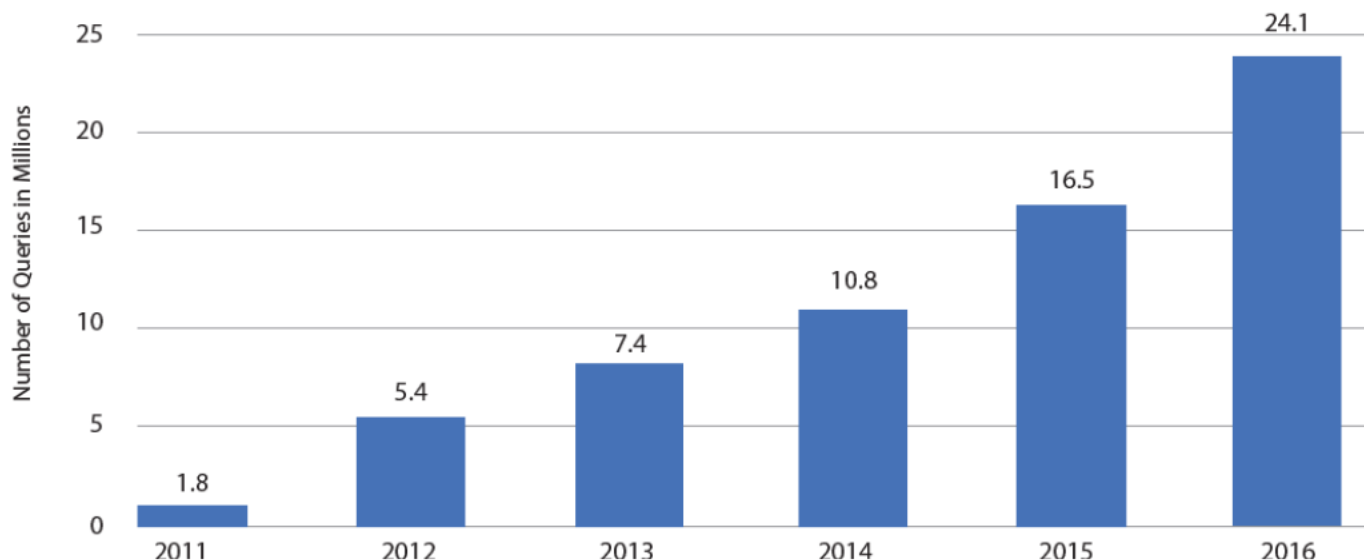
Source: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program.
 Multiple drugs are usually involved in overdose deaths. Individual deaths may be reported in more than one category.
 Includes Ohio residents who died due to unintentional drug poisoning (underlying cause of death ICD-10 codes X40-X44).
 * Excludes deaths involving fentanyl and related drugs.

Source: Ohio Department of Health. Drug Overdose Data and Publications. Retrieved September 29, 2017, from <http://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf?la=en> Department of Health & Human Services: <http://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf>

Ohio | 2016 Data

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Figure 5. Prescriber OARRS Queries, Ohio, 2011-2016

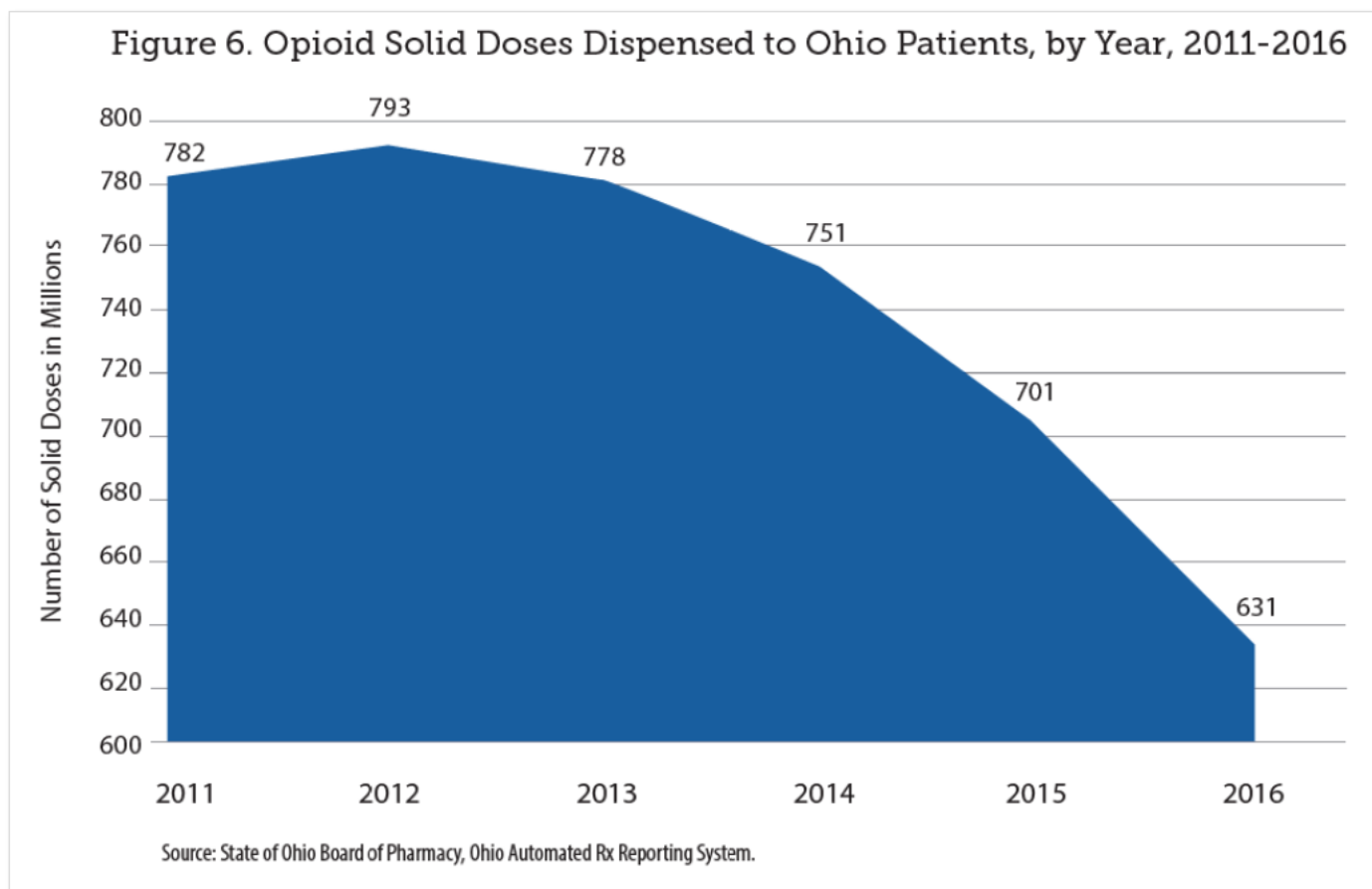


Source: State of Ohio Board of Pharmacy, Ohio Automated Rx Reporting System.

Source: Ohio Department of Health. Drug Overdose Data and Publications. Retrieved September 29, 2017, from <http://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf?la=en> Department of Health & Human Services: <http://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf>

Ohio | 2016 Data

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Source: Ohio Department of Health. Drug Overdose Data and Publications. Retrieved September 29, 2017, from <http://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf?la=en> Department of Health & Human Services: <http://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf>

Agenda



Scope of Problem

Industry Updates

Regulatory Responsibilities

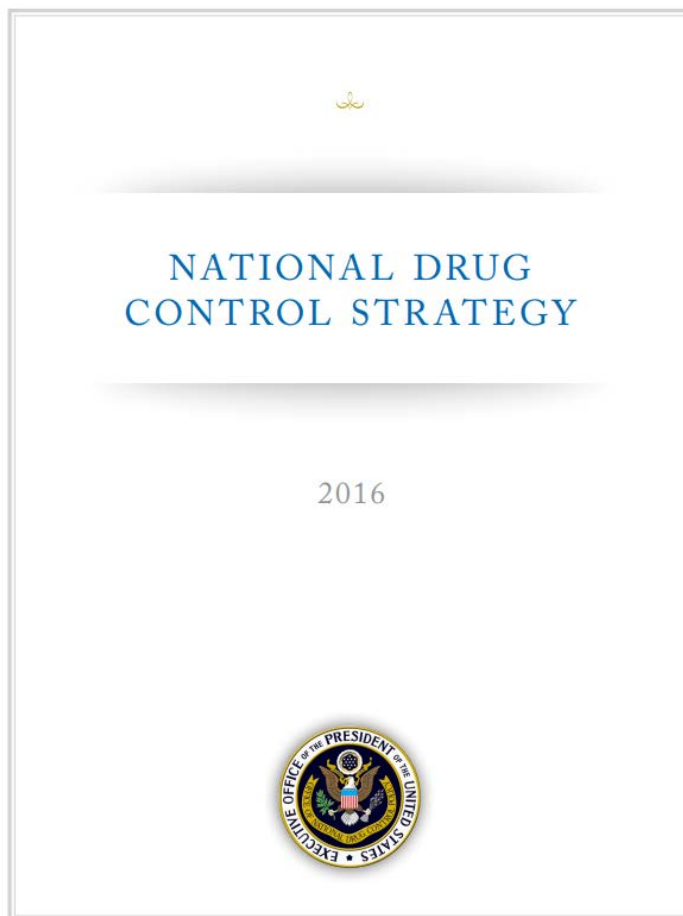
McKesson's CSMP

Discount Drug Mart Program Overview

Q & A | Open Discussion

Industry Updates | National Drug Control Strategy

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Policy Focus: Preventing and Addressing
Prescription Drug Misuse and **Heroin** Use


Four Pillars:

1. Education
2. Monitoring
3. Disposal
4. Enforcement

Source: Office of National Drug Control Policy. *2015 National Drug Control Strategy*. Retrieved February 10, 2016, from Office of National Drug Control Policy:
https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/2015_national_drug_control_strategy_0.pdf

Industry Updates | DEA 360 Strategy

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DEA 360 Strategy
Working Together to Break the Cycle of Drug Trafficking, Drug Violence, and Drug Abuse

What is DEA 360?
A comprehensive approach tackling the cycle of violence and addiction generated by the link between drug cartels, violent gangs, and the rising problem of prescription opioid and heroin abuse in U.S. cities. DEA 360 involves:

- Coordinated **Law Enforcement** operations targeting all levels of drug trafficking organizations and violent gangs supplying drugs to our neighborhoods
- Engaging drug manufacturers, wholesalers, practitioners, and pharmacists through **Diversion Control** to increase awareness of the opioid epidemic and encourage responsible prescribing practices, and use of opioid painkillers throughout the medical community
- Community Outreach** and partnership with local organizations following enforcement operations, equipping and empowering communities to fight the opioid epidemic

National Partners with Local Reach:

- U.S. Attorney's Office - Pittsburgh
- Boys & Girls Clubs of America
- Community Anti-Drug Coalitions of America
- DEA Educational Foundation
- DOJ - Violence Reduction Network
- The Elks Club
- HHS - Substance Abuse and Mental Health Services Administration
- White House Office of National Drug Control Policy
- Partnership for Drug-Free Kids

Goals:

- Stopping the deadly cycle of heroin and opioid pill abuse by eliminating drug trafficking organizations and gangs fueling violence on the streets and cycles of addiction in our communities
- Partnering with the medical community and others to raise awareness of the dangers of prescription opioid misuse and the link to heroin
- Strengthening community organizations best positioned to provide long-term help and support for building drug-free communities

Heroin/Prescription Opioid Overdose Epidemic: 120 Drug overdose deaths per day. 1/2 of those deaths are pharmaceutical opioids or heroin related.

For more information: Contact DEA Public Affairs at (202) 307-7977

Strategy for **prescription opioid** and **heroin** abuse:

- ✓ **Enforcement:** A commitment to stopping violence associated with drug trafficking
- ✓ **Diversion:** Enlisting DEA's registrant population in the fight against opioid abuse
- ✓ **Community:** Leaving something lasting and positive in the communities DEA serves

Pilot in West Memphis, AR, St. Louis, MO, Pittsburgh, PA, Milwaukee, WI

Source: Statement of Louis J. Milione, Deputy Assistant Administrator, Office of Diversion Control, DEA before the Committee on the Judiciary, United States Senate, for a Hearing entitled "Attacking America's Epidemic Of Heroin And Prescription Drug Abuse" presented January 27, 2016. <http://www.dea.gov/divisions/hq/2015/hq111015-DEA%20360%20Strategy%20Fact%20Sheet.pdf>, Accessed February 10, 2016.

Industry Updates | Today's Heroin Epidemic

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Vital signs™ JULY 2015

Today's Heroin Epidemic

More people at risk, multiple drugs abused

Heroin use has increased across the US among men and women, most age groups, and all income levels. Some of the greatest increases occurred in demographic groups with historically low rates of heroin use: women, the privately insured, and people with higher incomes. Not only are people using heroin, they are also abusing multiple other substances, especially cocaine and prescription opioid painkillers. As heroin use has increased, so have heroin-related overdose deaths. Between 2002 and 2013, the rate of heroin-related overdose deaths nearly quadrupled, and more than 8,200 people died in 2013. States play a central role in prevention, treatment, and recovery efforts for this growing epidemic.

States can:

- Address the strongest risk factor for heroin addiction: addiction to prescription opioid painkillers.
- Increase access to substance abuse treatment services, including Medication-Assisted Treatment (MAT), for opioid addiction.
- Expand access to and training for administering naloxone to reduce opioid overdose deaths.
- Ensure that people have access to integrated prevention services, including access to sterile injection equipment from a reliable source, as allowed by local policy.
- Help local jurisdictions to put these effective practices to work in communities where drug addiction is common.

Want to learn more? www.cdc.gov/vitalsigns/heroin

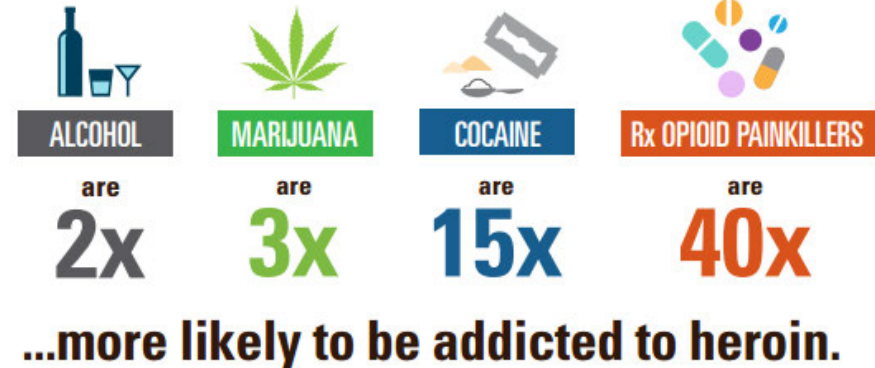
2x
Heroin use more than doubled among young adults ages 18–25 in the past decade.

9 in 10
More than 9 in 10 people who used heroin also used at least one other drug.

45%
45% of people who used heroin were also addicted to prescription opioid painkillers.

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

People who are addicted to...

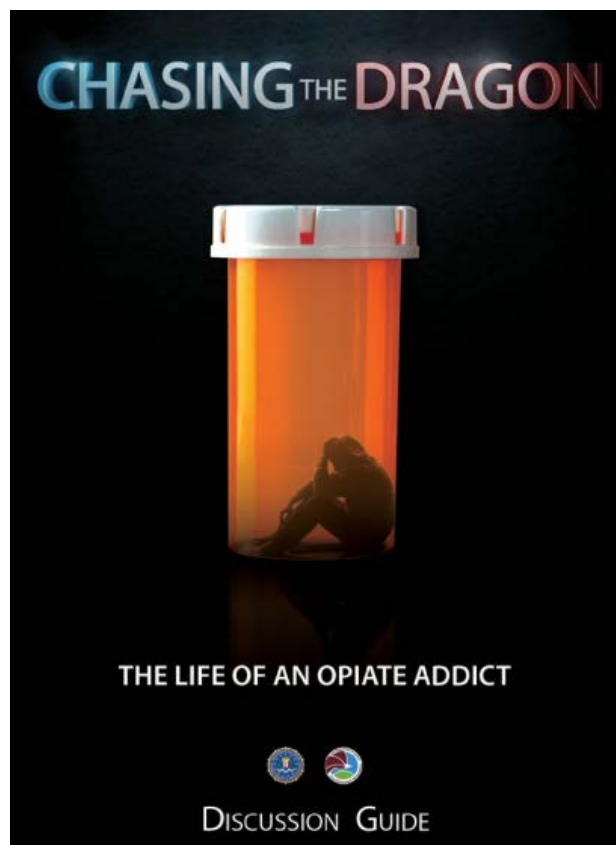


SOURCE: National Survey on Drug Use and Health (NSDUH), 2011–2013.

Source: Centers for Disease Control and Prevention, Vital Signs July 2015. *Today's Heroin Epidemic*. Retrieved February 10, 2016, from Centers for Disease Control and Prevention: <http://www.cdc.gov/vitalsigns/pdf/2015-07-vitalsigns.pdf>

Industry Updates | Chasing the Dragon

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Chasing the Dragon is a documentary film from DEA and FBI;

- ✓ Aimed at educating high school students & young adults of the dangers of addiction
- ✓ Message is deterrence since opioid addiction can take hold after first use

Source: FBI National Press Office. *FBI, DEA Release Documentary Film Addressing Heroin/Prescription Drug Abuse*. Retrieved February 10, 2016, from FBI: <https://www.fbi.gov/news/pressrel/press-releases/fbi-dea-release-documentary-film-addressing-heroin-prescription-drug-abuse>

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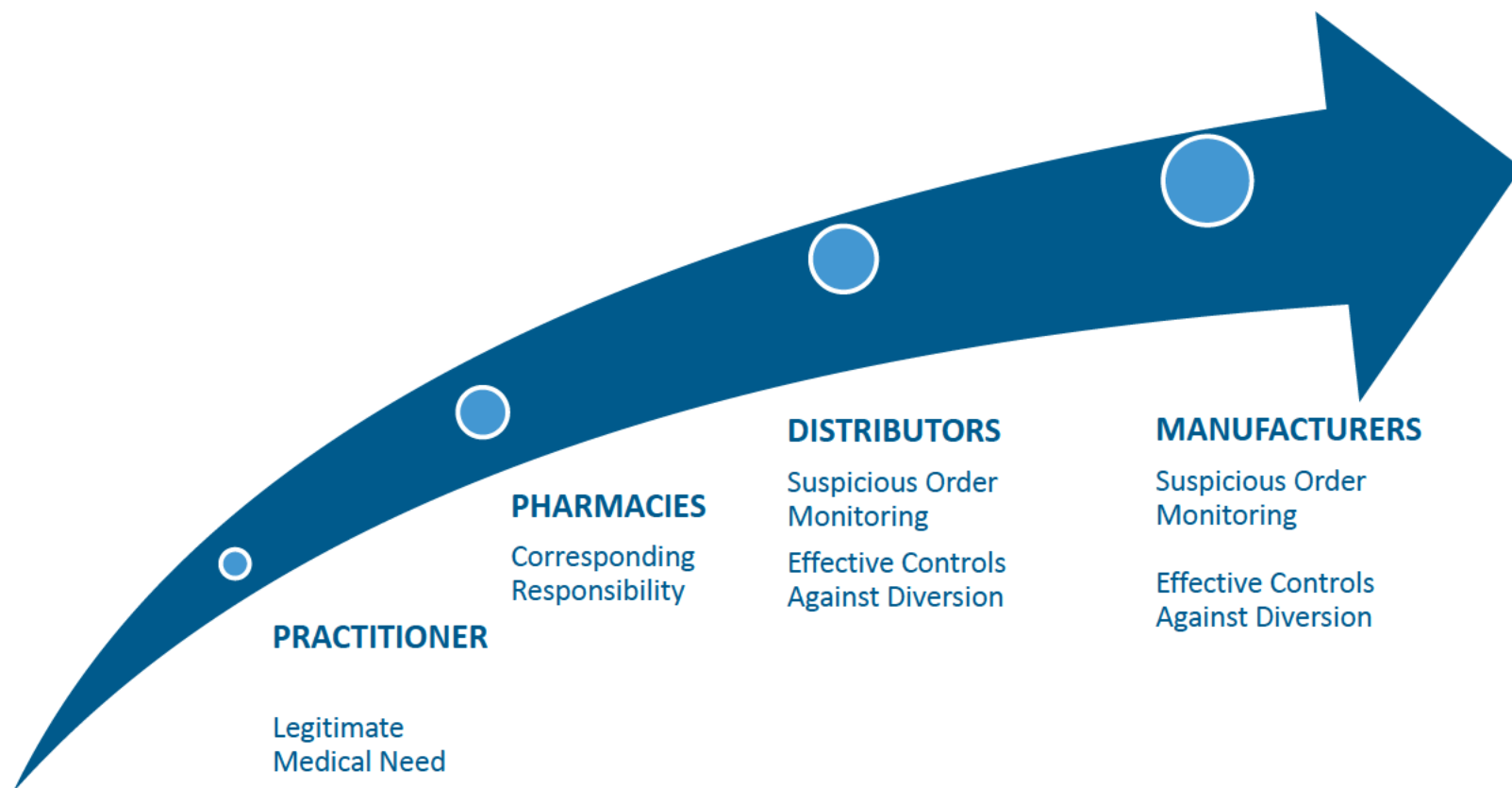
Discount Drug Mart Program Overview

Q & A | Open Discussion

Regulations | The Supply Chain

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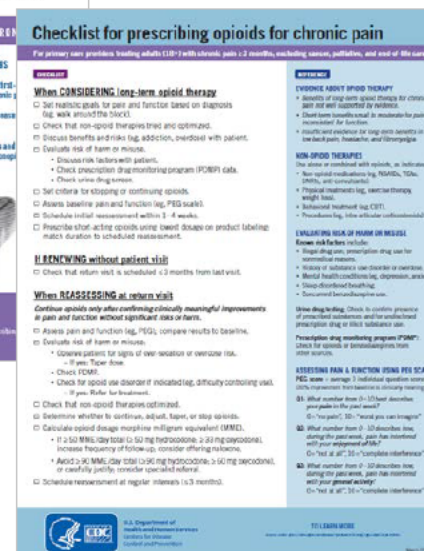
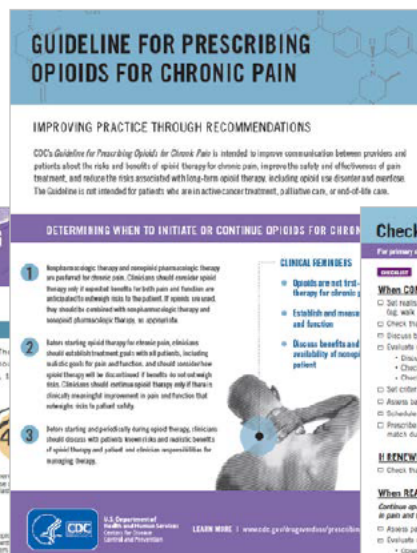
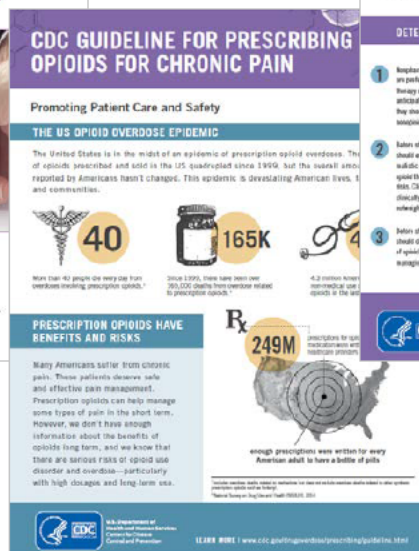
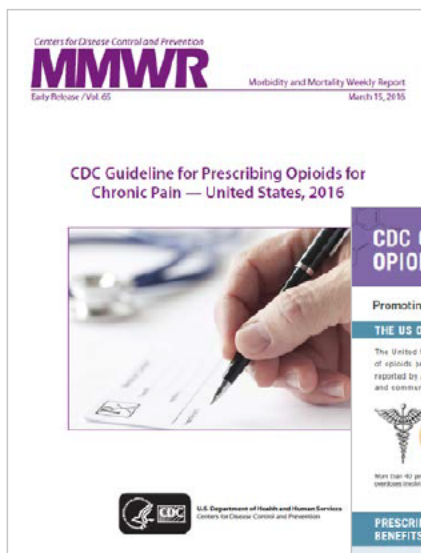
*Prescription drug abuse is a **national problem**, requiring an **industry-wide solution**.*



CSA Checks & Balances | Practitioners

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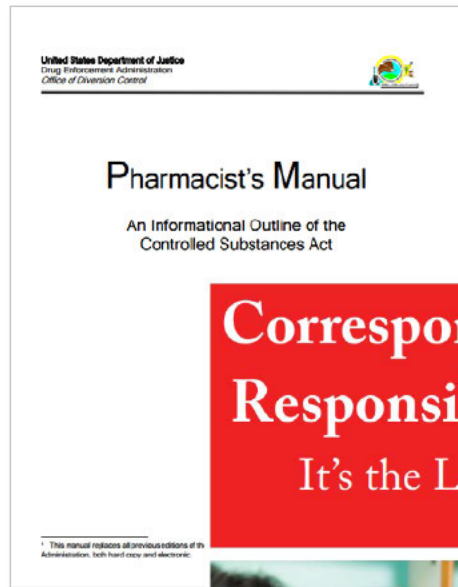
*"A prescription for a controlled substance to be effective must be issued for a **legitimate medical purpose** by an individual practitioner acting in the usual course of professional practice."* (21 CFR §1306.04(a))



CSA Checks & Balances | Pharmacists

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*"The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility** rests with the **pharmacist** who fills the prescription."* (21 CFR § 1306.04(a))



**Corresponding
Responsibility**
It's the Law.

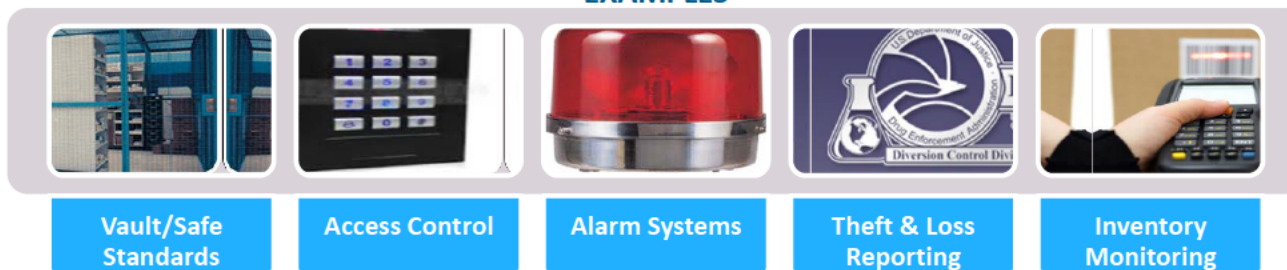


CSA Checks & Balances | Distributors & Manufacturers

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*“Maintenance of **effective controls against diversion** of particular controlled substances into other than legitimate medical, scientific, and industrial channels...” (21 U.S.C. §823/21 CFR §1301.71(a))*

EXAMPLES



*“The registrant shall **design** and **operate** a system to disclose to the registrant **suspicious orders** of controlled substances. . . . Suspicious orders include orders of unusual **size**, orders deviating substantially from a normal **pattern**, and orders of unusual **frequency**.” (21 CFR §1301.74(b))*

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McKesson's CSMP

Discount Drug Mart Program Overview

Q & A | Open Discussion

McKesson CSMP | Mission & Operating Principles

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U.S. Pharma Controlled Substance Monitoring Program

Mission Statement

Our mission is to manage U.S. Pharma's Controlled Substance Monitoring Program as a nationwide regulatory compliance program that is informed by diversion trends and our customers. Through our program, we strive to strengthen the understanding of the prescription drug abuse epidemic across the industry with dialogue and collaboration.

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U.S. Pharma Controlled Substance Monitoring Program

Operating Principles

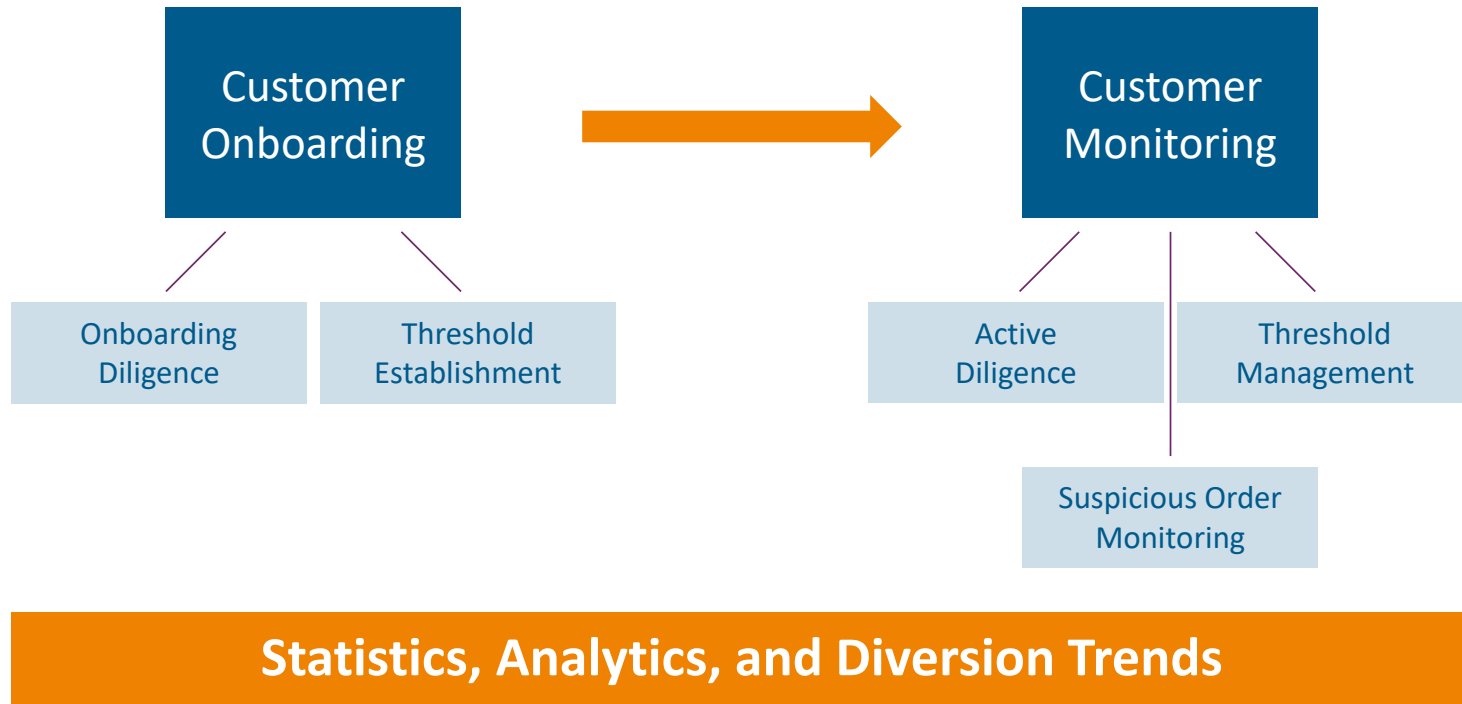
As we continue to design our program, we will adhere to the following operating principles:

- **Risk-based** — Comprehensively covers all controlled substances and all customers, while driving the greatest focus on those presenting a higher risk of diversion.
- **Uniform** — Generates consistent execution against nationwide standards and requirements.
- **Sustainable** — Achievable over the long term.
- **Contemporary** — Refreshed on an ongoing basis to address current diversion trends, while reflecting the legitimate business models of our customers as they evolve.
- **Defined** — Meets regulations as they are applicable to wholesalers. Other registered entities in the supply chain have their own independent responsibility to achieve compliance.

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McKesson CSMP | Design/Framework

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McKesson CSMP | RNA Team

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Nate Hartle
 Sr. Director
 Minneapolis, MN



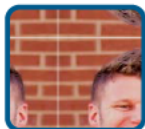
Michael Oriente
 Director
 Philadelphia, PA



Adam Palmer
 Sr. Manager
 Indianapolis, IN



Micheal Bishop
 Manager
 Las Colinas, TX



Adam Shepherd
 Regulatory Assistant
 Las Colinas, TX

Sr. Director Leadership Background:

- ✓ Retail Diversion
- ✓ Special Investigations
- ✓ Data, Analytics & Intelligence
- ✓ Industry Leadership

Team Backgrounds / Skill Sets:

- ✓ Regulatory Affairs
- ✓ Retail Diversion Analytics & Investigations
- ✓ Internal Data & Systems
- ✓ Distribution Center Operations
- ✓ Retail National Account Experience
- ✓ Project Management
- ✓ Clinical Research Compliance

McKesson CSMP | Diligence – “Know Our Customer”

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McKesson CSMP | Onboarding & Monitoring

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Onboarding

Chain Diligence:

- ✓ Pharmacy Operations
- ✓ CS Compliance Program & Policies
- ✓ Business Model / Processes
- ✓ Dispensing Data Review

Registrant Diligence:

- ✓ Licensure & Registration
- ✓ Questionnaires (If Applicable)
- ✓ Dispensing Data (If Applicable)

Threshold Establishment

Monitoring

Ongoing Diligence:

- ✓ Event Triggered Reviews
- ✓ Data Analysis - Outlier Identification
- ✓ HQ Follow Up / Site Visits

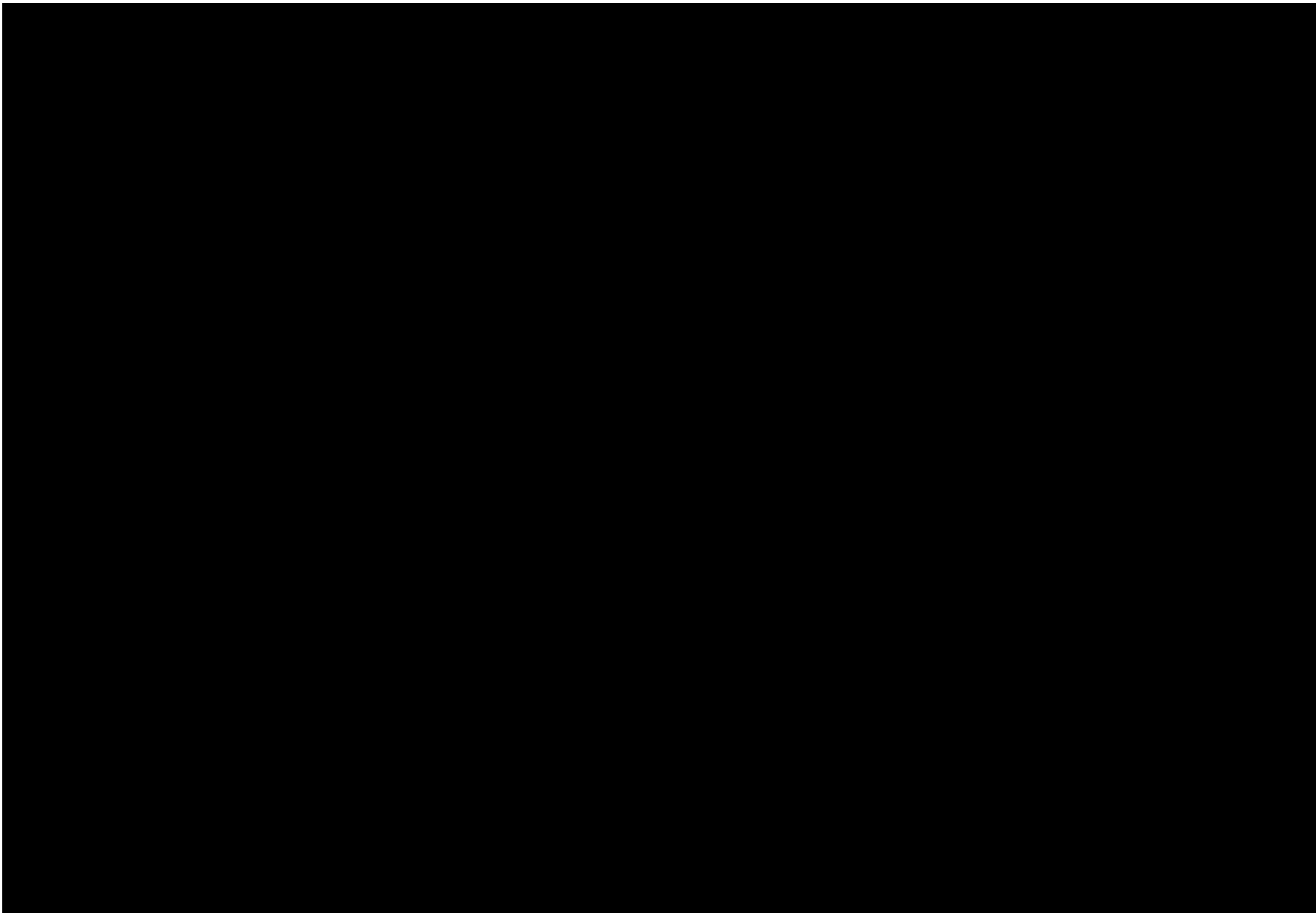
Threshold Management (TCRs):

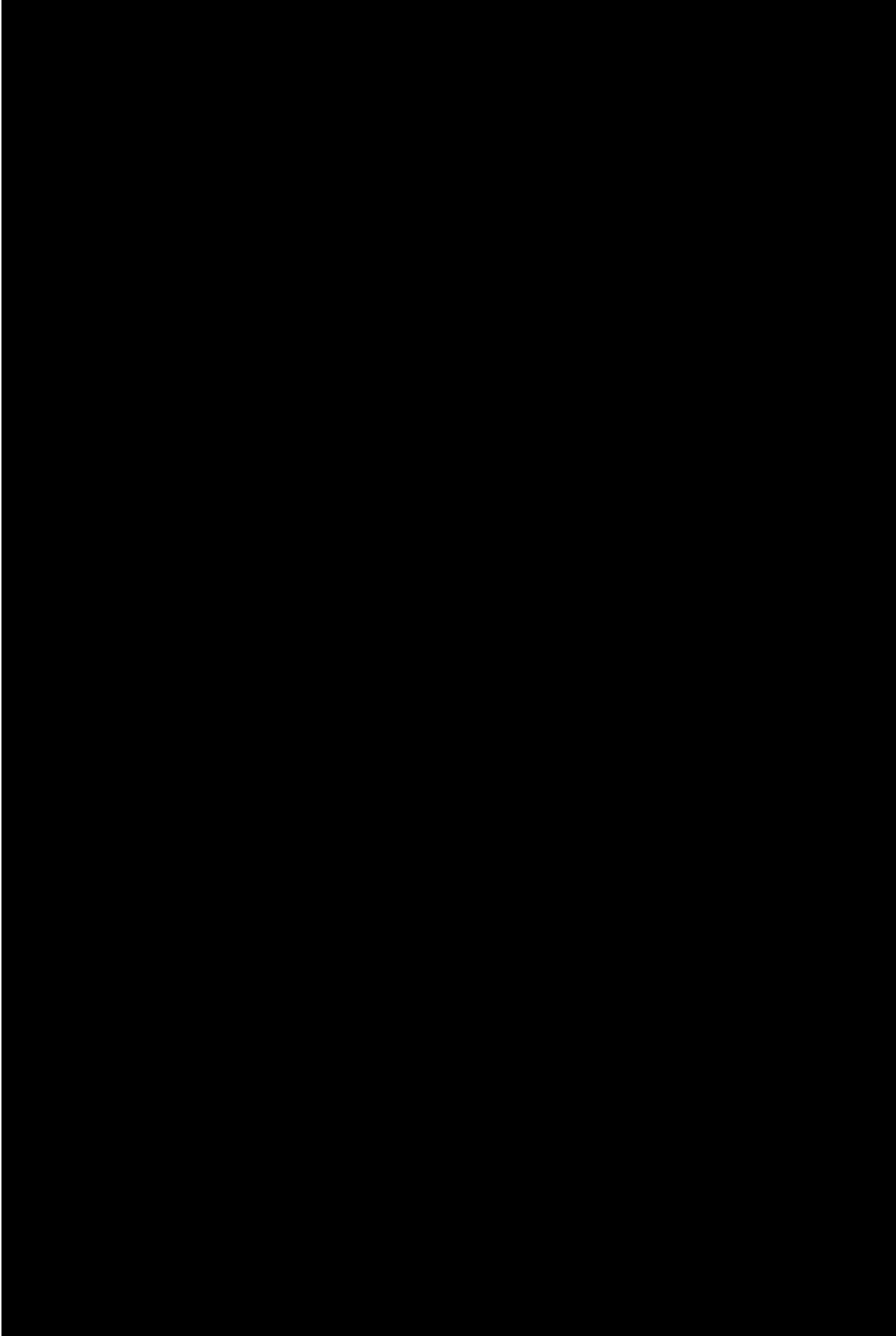
Business Justification

- ✓ Dispensing Data
- ✓ Independent Retail Specific
 - Recent Questionnaire (12M)
 - Personnel Information

Suspicious Order Reporting

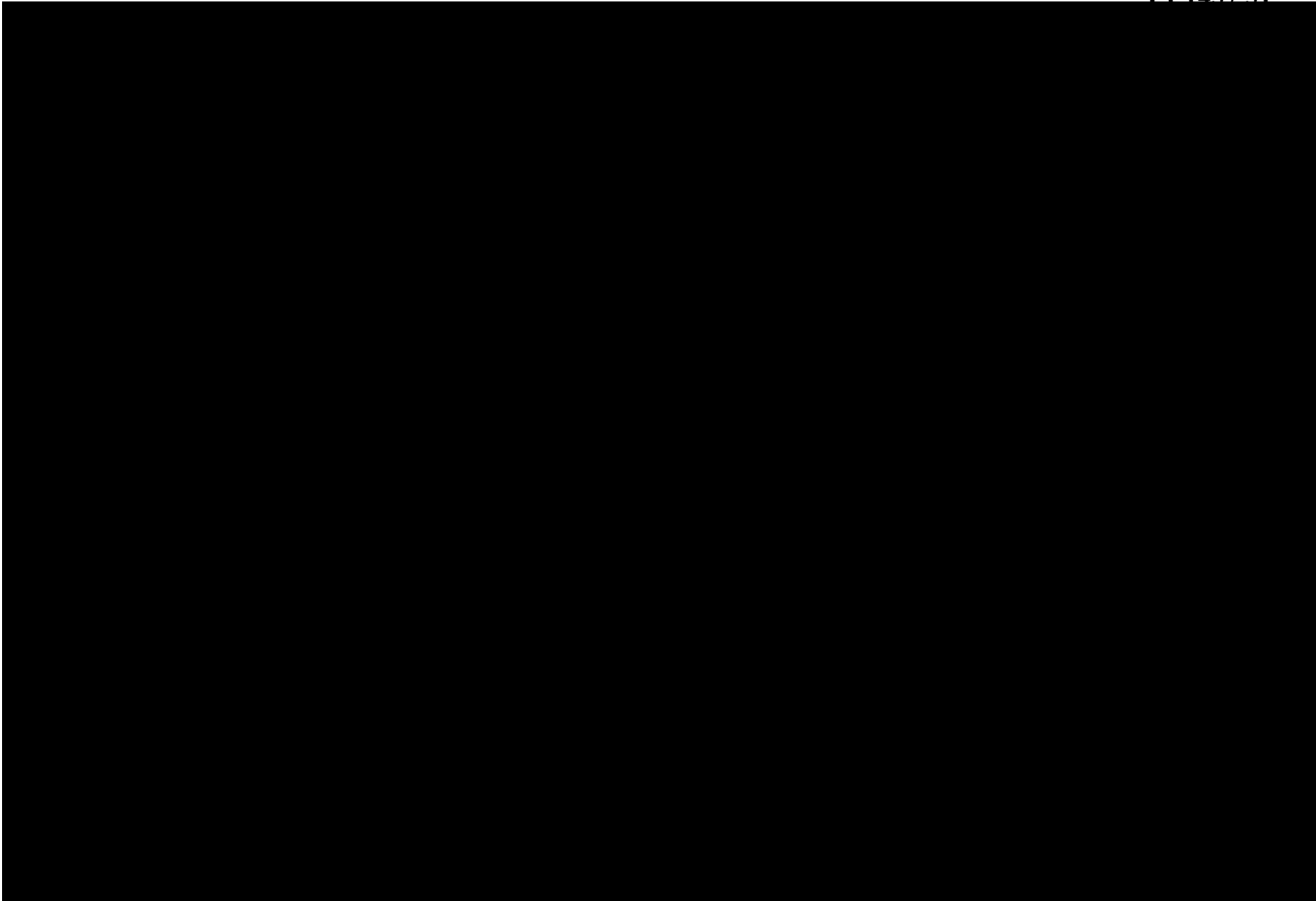
Statistics, Analytics & Diversion Trends

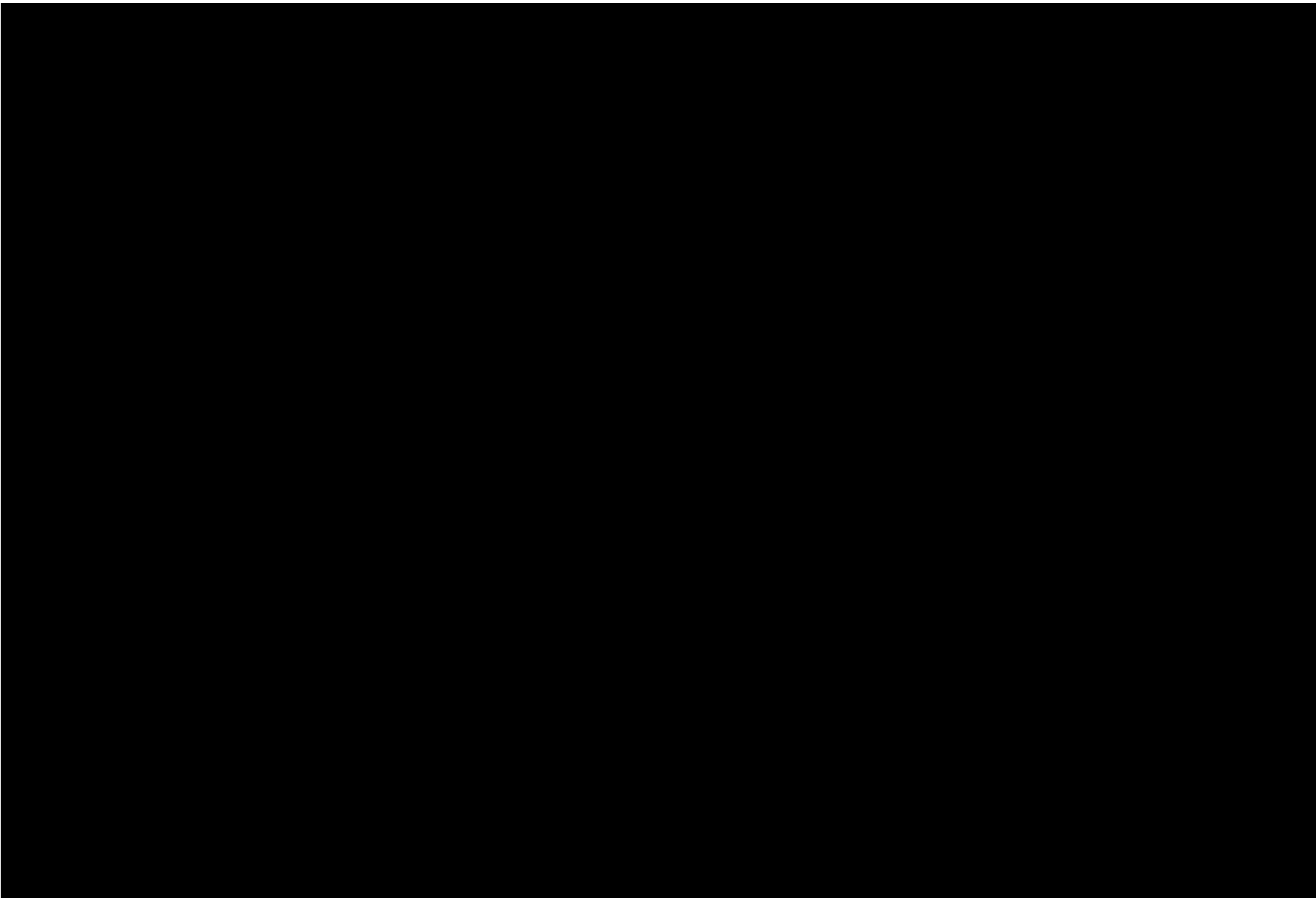


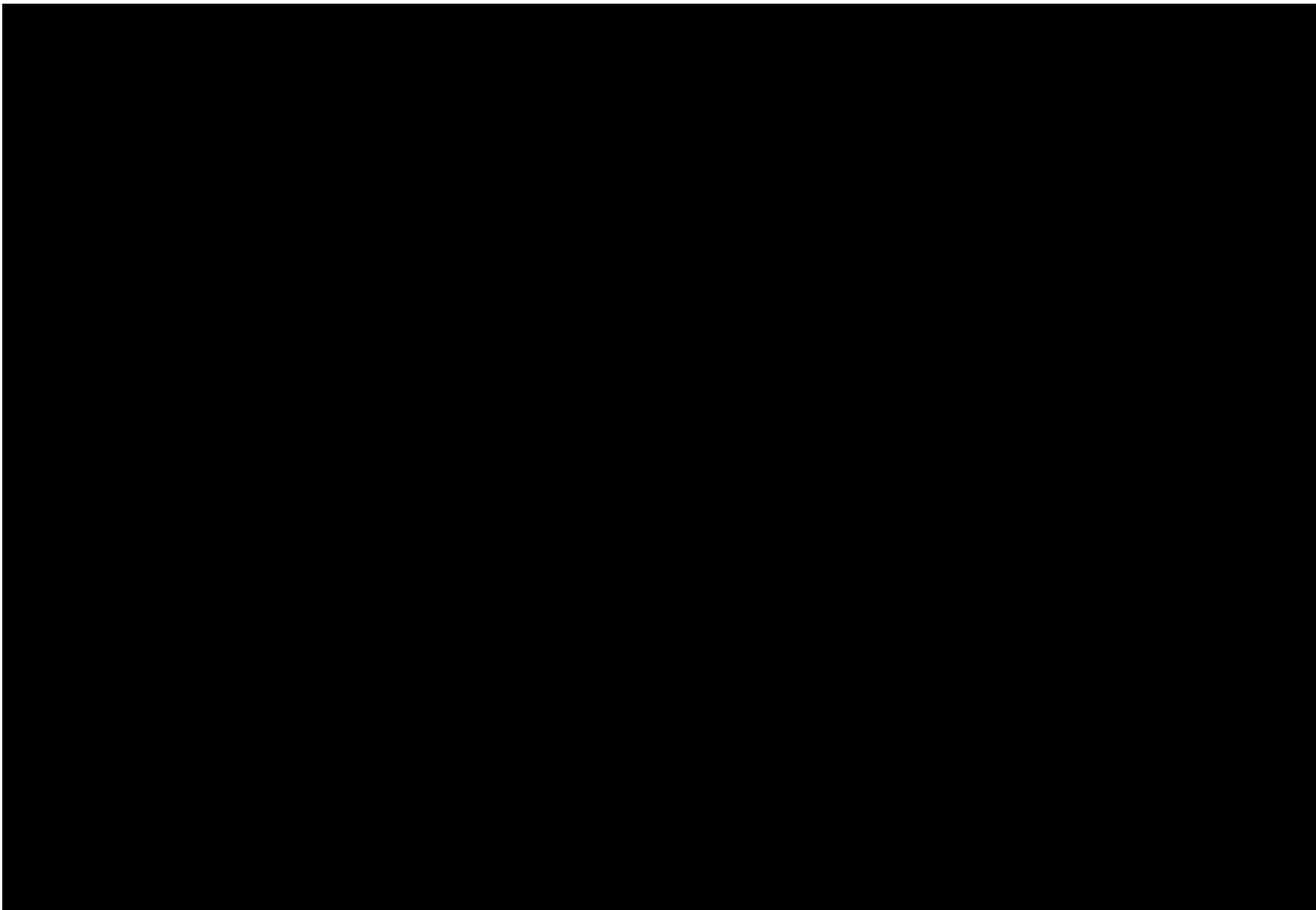


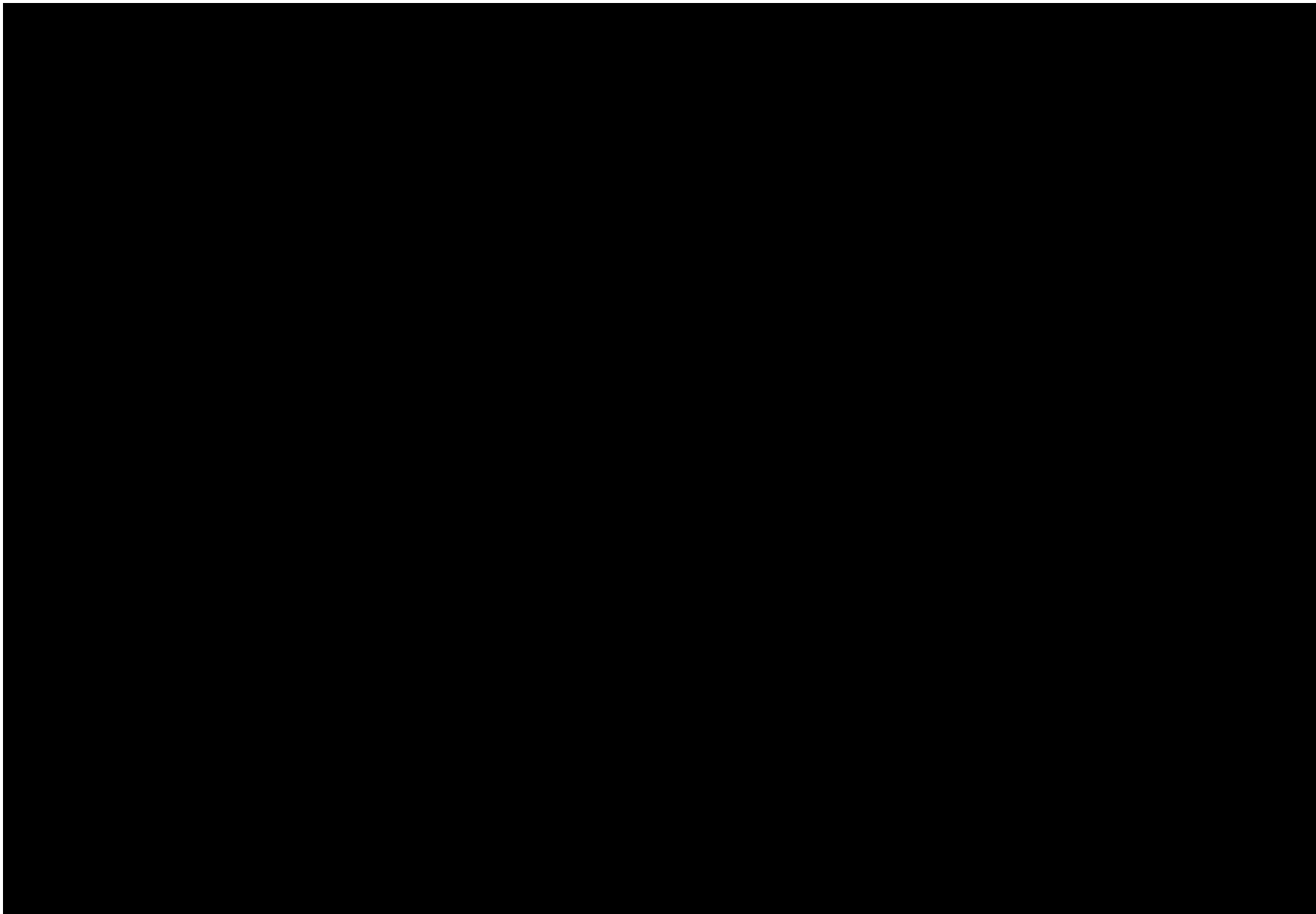
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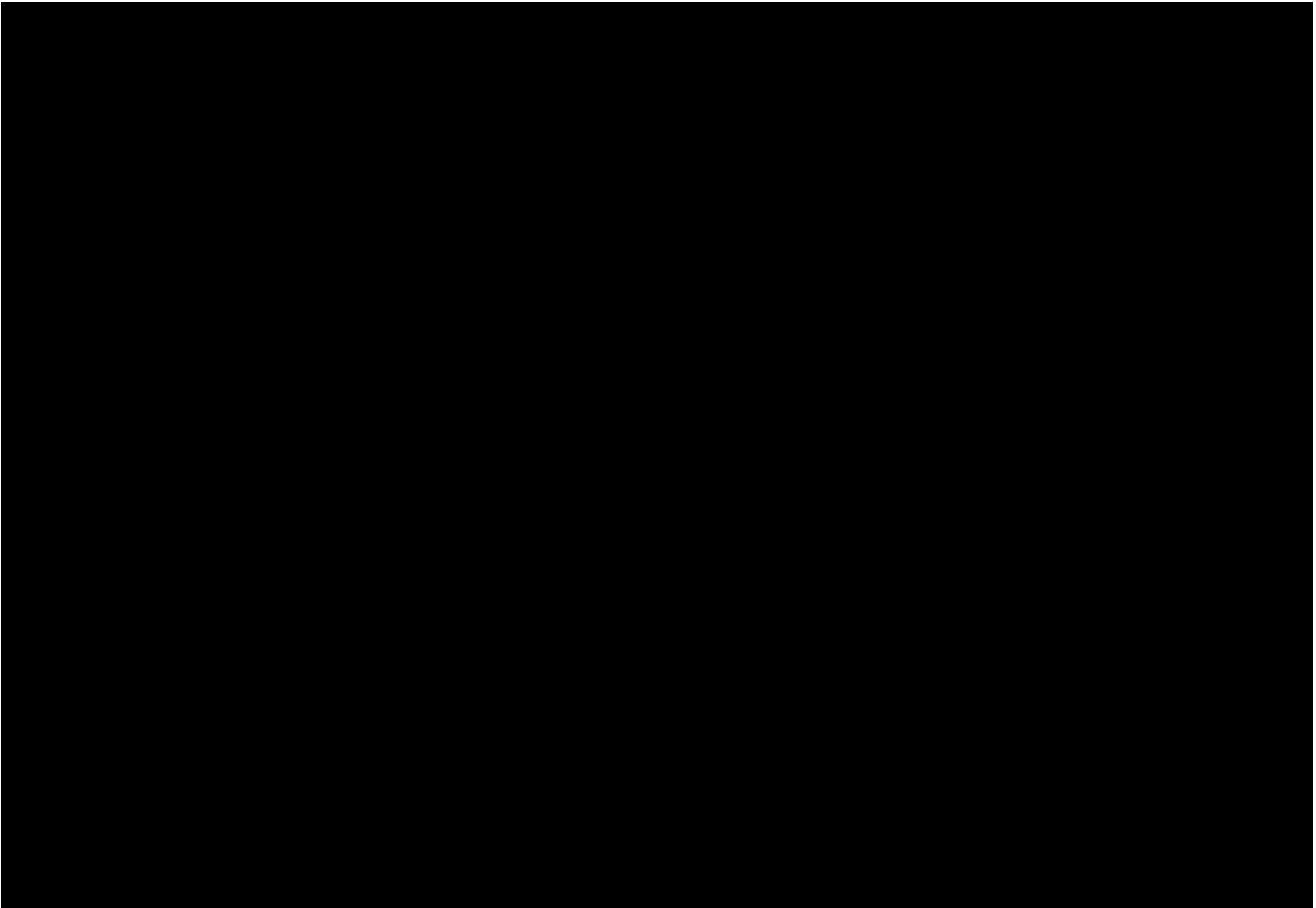
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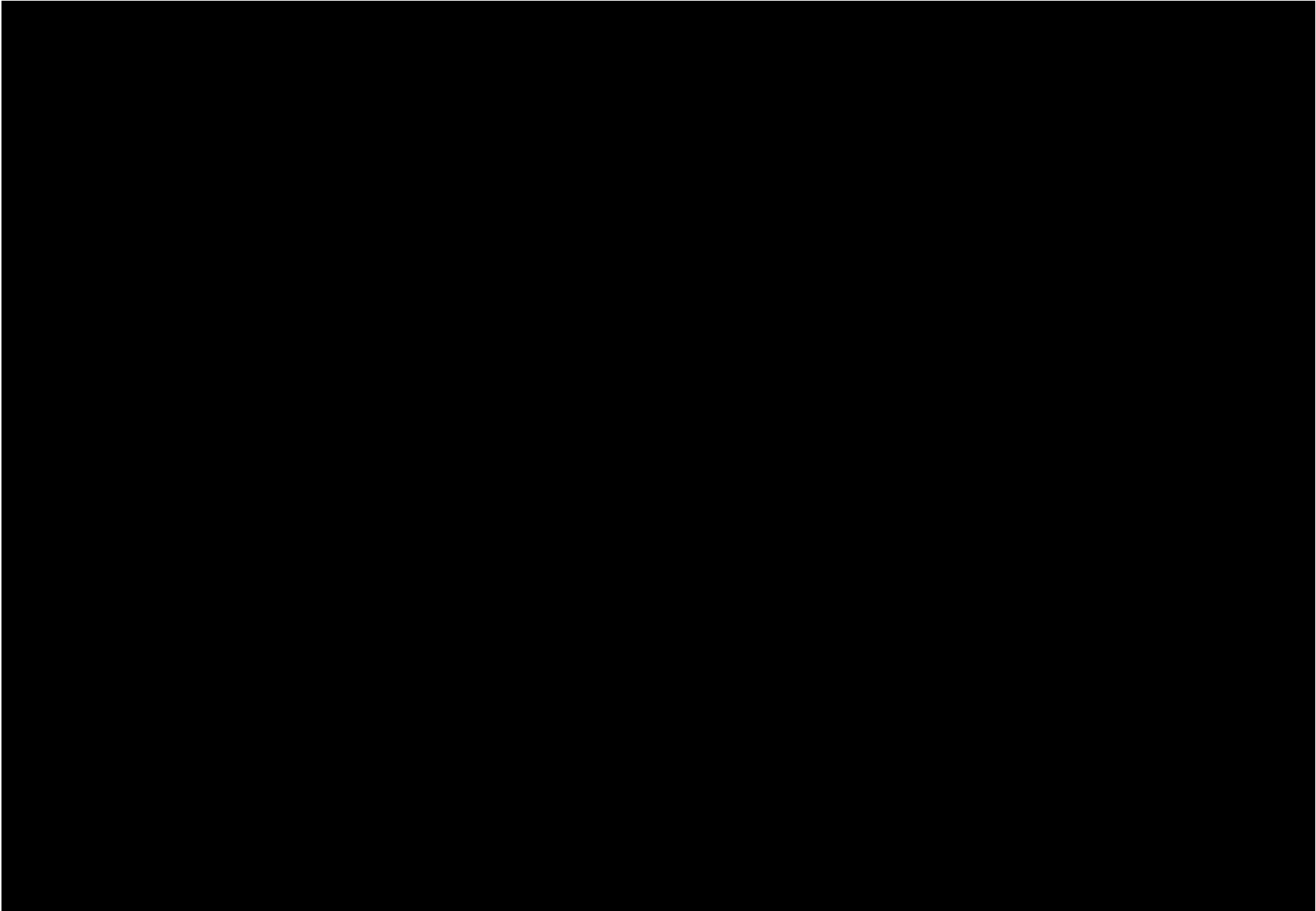


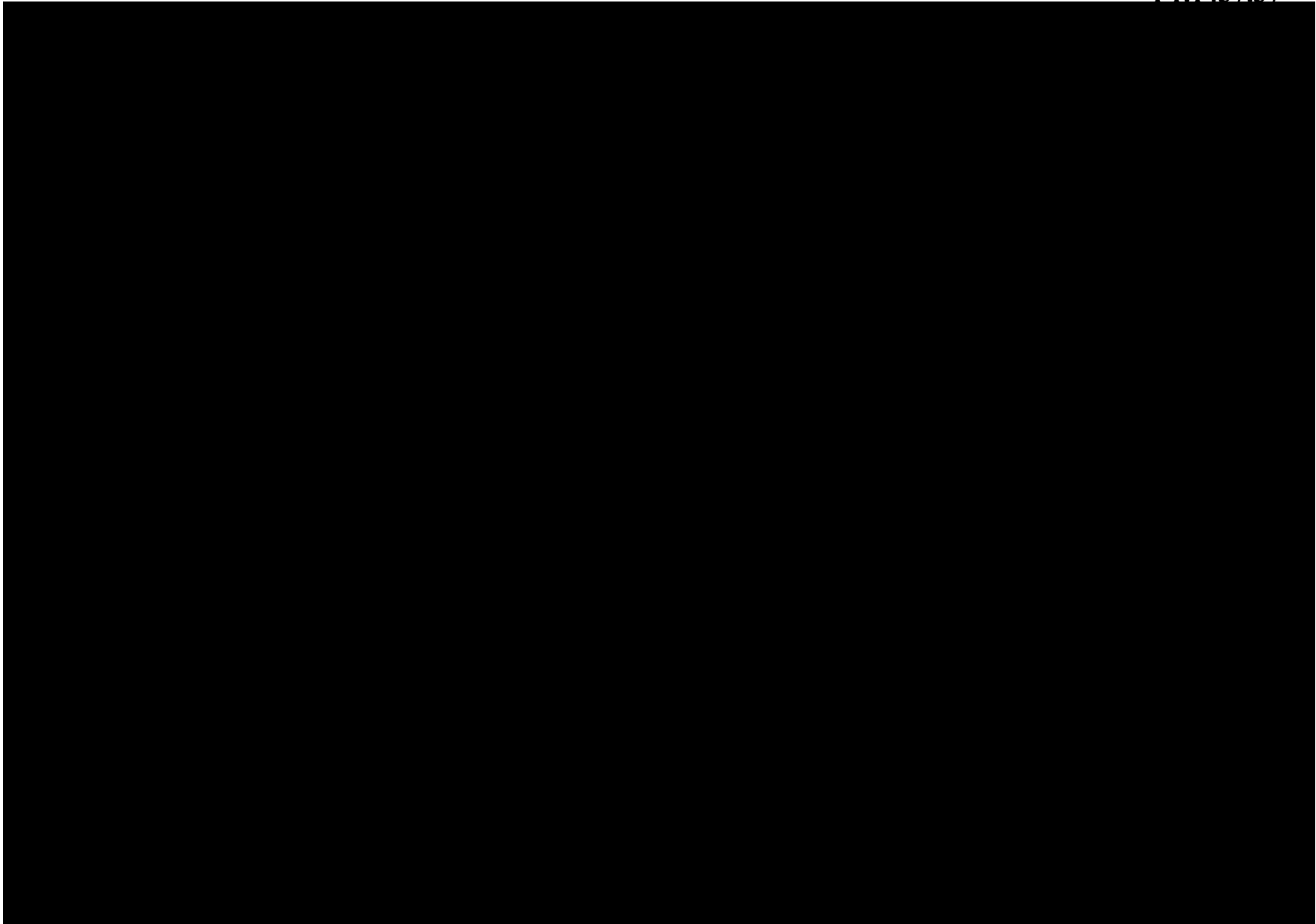










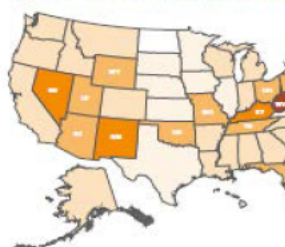


McKesson CSMP | Education & Awareness

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Prescription Drug Abuse Landscape

Current Drug Abuse Trends
Overdose Mortality Rates per 100,000 People (2010)



**This includes all drug deaths from prescription drugs, heroin, cocaine, etc.
Source: American Medical Association, Prescription Drug Abuse: Strategies to Stop the Epidemic

What Can You Do? Practical Tips

DEA registrants are **always** responsible for meeting their responsibility for monitoring and ensuring the appropriate use of controlled substances. For pharmacists and pharmacy owners, this means ensuring corresponding responsibility to determine that prescriptions are for legitimate medical purposes by practitioners acting in the usual course of practice. One way in which the pharmacist and pharmacy owner can practice is to better understand their controlled substance data to circumstantially determine if diversion may be occurring.

1. **Closely monitor the drugs of concern.** All controlled substances, with those in schedule II having a higher potential for abuse, are the more commonly diverted controlled substances: hydrocodone, hydromorphone, oxycodone, alprazolam, and others.
2. **Know your pharmacy's ordering patterns.** What is your typical quantity of controlled substances? What is your typical dose? Maintaining awareness will help you recognize

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Red Flags

There are numerous "red flags" indicating possible prescription drug misuse, abuse and diversion. Some common red flags suggested by the DEA and certain state boards of pharmacy include:

Pattern Prescribing

Pharmacists need to be particularly alert for prescriptions for the same drugs, quantities or diagnosis codes coming from the same doctor. Further, the use of rubber stamps is another key red flag.

Antagonistic Drugs

Look for prescriptions written for antagonistic drugs (e.g., depressants and stimulants).

Drug Cocktails

Flag and scrutinize prescriptions for drug cocktails (e.g., opioids with benzodiazepines and/or carisoprodol).

Large Quantities

Look at the quantities. High doses and/or high quantities of drugs are often a key indicator of abuse.

Doctor Patterns

Be on the lookout for doctors that write significantly more prescriptions compared to other doctors in your area.

Beyond Specialty

Question prescriptions written by doctors for infirmaries not consistent with their area of specialty (e.g., dentist writing ADHD prescriptions).

Geographic Flags

Notice geographic anomalies, such as prescriptions written by a local prescriber for out-of-state patients, or situations in which the pharmacy is not near the patient or the prescriber.

Unlikely Coincidences

Situations such as customers with shared addresses presenting similar prescriptions from the same physician on the same day can also prove fraudulent.

False Caregivers

Further, you will want to scrutinize customers presenting prescriptions for other people.

Cash Payments

Customers paying cash may require additional scrutiny.

Early Refills

Customers requesting early refills of controlled substances should be questioned and may require additional scrutiny.

Suspicious Behavior

Look for signs of nervousness such as being overly talkative, agitated, emotionally volatile, evasive, etc.

Signs of Forgery

Fraudulent or forged prescriptions can often be identified by the following characteristics:

- False contact information
- Misspellings
- Photocopies
- Alterations to prescriptions
- Different inks or handwriting
- Quantity, directions or dosages differ from usual medical usage
- No abbreviations used or non-standard abbreviations

This national Automation Benchmark in assessing drug use is based on the DEA's 2012 ARCOS data.**

Things don't look right, as practitioner and use your board of pharmacy's website as a reputation as being a source and ensure that you

es controlled substances has pharmacies to be the last in working together with its

Medication	Dosage Units Annually
Hydrocodone	131,581
Oxycodone	75,584
Methadone	12,800
Morphine	11,768
Hydromorphone	5,903
Oxycodone	2,190

**These numbers are not guidelines for appropriate dosing. They are simply national averages derived from the DEA's ARCOS data. Overdose can occur in purchases below the DEA national averages.

"Flags" indicating possible prescription drug misuse, some common red flags suggested by the DEA and certain state boards of pharmacy include:

Particularly alert for prescriptions for the same drugs, quantities or diagnosis codes coming from the same doctor, the use of rubber stamps is another key red flag.

Look for prescriptions written for antagonistic drugs (e.g., depressants and stimulants).

Look at the quantities. High doses and/or high quantities of drugs are often a key indicator of abuse.

Be on the lookout for doctors that write significantly more prescriptions compared to other doctors in your area.

Question prescriptions written by doctors for infirmaries not consistent with their area of specialty (e.g., dentist writing ADHD prescriptions).

Notice geographic anomalies, such as prescriptions written by a local prescriber for out-of-state patients, or situations in which the pharmacy is not near the patient or the prescriber.

Unlikely Coincidences

Situations such as customers with shared addresses presenting similar prescriptions from the same physician on the same day can also prove fraudulent.

False Caregivers

Further, you will want to scrutinize customers presenting prescriptions for other people.

Cash Payments

Customers paying cash may require additional scrutiny.

Early Refills

Customers requesting early refills of controlled substances should be questioned and may require additional scrutiny.

Suspicious Behavior

Look for signs of nervousness such as being overly talkative, agitated, emotionally volatile, evasive, etc.

Signs of Forgery

Fraudulent or forged prescriptions can often be identified by the following characteristics:

- False contact information
- Misspellings
- Photocopies
- Alterations to prescriptions
- Different inks or handwriting
- Quantity, directions or dosages differ from usual medical usage
- No abbreviations used or non-standard abbreviations

Agenda



Scope of Problem

Industry Updates

Regulatory Responsibilities

McKesson's CSMP

Discount Drug Mart Program Overview

Q & A | Open Discussion

Controlled Substances | Discount Drug Mart CSMP

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Discussion Topics:

- Overview of Pharmacy Business
- Regulatory/Compliance Structure
- Policies & Procedures
- Training & Education
- Analytics, Monitoring & Follow Up
- Known Outliers

Q & A

